K042169

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

Trade Name: Sirrus® Clinical Chemistry Analyzer

Common/Classification Name: Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

Device Classification: Class: I
CFR: 21 CFR 862.2160
Product Code: JJE

MAR 1 4 2005

Manufacturer:
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006
830 249-0772

Device Description:
The Sirrus® Clinical Chemistry Analyzer is an automated system for quantitative analysis of clinical chemistries. The analyzer is intended for clinical use in conjunction with certain materials to measure a variety of analytes.

Intended Use:
Per 21 CFR 862.2160, the Sirrus® Clinical Chemistry Analyzer is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

Substantial Equivalence:
Substantial equivalence has been demonstrated between the Sirrus® Clinical Chemistry Analyzer and the Roche Cobas Mira® (K920402).

Comparison To Predicate Device:

Correlation:
A correlation analysis between the Stanbio Laboratory Sirrus® Clinical Chemistry Analyzer and the Roche Cobas Mira Plus yielded the following results:

Assay	Correlation Coefficient	Slope	Y-axis intercept
Glucose	0.9971	0.887	16.17 mg/dL
Cholesterol	0.9894	1.126	-24.90 mg/dL
Triglycerides	0.9978	0.972	-5.03 mg/dL

Precision:
Within Run:

Assay	Mean	Standard Deviation	% CV
Glucose (Sam #1)	94 mg/dL	1.57	1.67 %
Glucose (Sam #2)	270 mg/dL	2.61	0.97 %

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS cont'd

Within Run cont'd

Assay	Mean	Standard Deviation	% CV
Cholesterol (Sam #1)	143 mg/dL	1.50	1.05 %
Cholesterol (Sam #2)	242 mg/dL	2.68	1.11 %
Triglycerides (Sam #1)	78 mg/dL	1.35	1.73 %
Triglycerides (Sam #2)	183 mg/dL	1.79	0.98 %

Between Run:

Assay	Mean	Standard Deviation	% CV
Glucose (Sam #1)	100 mg/dL	2.23	2.22 %
Glucose (Sam #2)	302 mg/dL	4.86	1.61 %
Cholesterol (Sam #1)	154 mg/dL	6.15	3.99 %
Cholesterol (Sam #2)	263 mg/dL	4.17	1.58 %
Triglycerides (Sam #1)	86 mg/dL	2.86	3.30 %
Triglycerides (Sam #2)	208 mg/dL	5.56	2.67 %

Conclusion / Substantial Equivalence:
The Stanbio Laboratory Sirrus® Clinical Analyzer and the predicate device, Roche Cobas Mira®, are substantially equivalent based on design and function.

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 4 2005

Mr. Kirk Johnson
QA/ Regulatory Affairs Manager
Stanbio Laboratory
1261 North Main St.
Boerne TX, 78006

Re: k042169
Trade/Device Name: Sirrus Clinical Chemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, CHH, CDT, JJE
Dated: January 15, 2005
Received: February 1, 2005

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042169

Device Name: Sirrus Clinical Chemistry Analyzer

Indications For Use:

The Sirrus® Clinical Chemistry Analyzer is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by automatically various steps such as pipetting, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes to include Glucose, Cholesterol, and Triglycerides.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson

Office of In Vitro Diagnostic Device Evaluation and Safety

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